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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/284,100	04/07/99	NARHI	L A-423C

HM22/0609

U S PATENT OPERATIONS TDZ
AMGEN INCORPORATION
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THOUSAND OAKS CA 91320-1799

EXAMINER	
HAMUD, F	
ART UNIT	**PAPER NUMBER**
1646	4
DATE MAILED:	06/09/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

Office Action Summary

Application No.	Applicant(s)
09/284,100	Narhi et al.
Examiner	**Group Art Unit**
Fozia Hamud	1646

☒ Responsive to communication(s) filed on *Apr 7, 1999*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-24* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-24* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. This application is a 371 of PCT/ US97/18607. For applications filed under 371, PCT rules for lack of unity apply.

2. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1, and restriction to one of the groups is required.

I. Claims 1-22, drawn to variants of KGF-2, polynucleotides encoding said variants, vectors comprising said polynucleotides, host cells transfected with said vectors and a method of producing said variants.

II. Claims 23-24, drawn to a method of stimulating the production of epithelial cells, comprising contacting such cells with an effective amount of a variant of KGF-1.

The inventions listed as Groups I-II do not meet the requirements for Unity of Inventions for the following reasons: The invention of Group I is separate and distinct from the invention of Group II because the invention of Group I may be used in other methods other than that of Group II, such as the variants of Group I can be used as antigens in production of antibodies or can be used diagnostically or therapeutically.

Claims 1-2 and 4 of the instant application recite various species of variants of KGF-2 that do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the variants lack the same or corresponding special technical features for the following reasons:

The special technical features which define them by chemical and physical characteristics, i.e structure/function, as well as biological functions are different and these special technical features are not shared by each variant. Therefore, Applicants must elect:

1) One of the following variants: ∇N41 KGF-2, ∇N40 KGF-2, ∇N39 KGF-2,∇N38 KGF-2, ∇N37 KGF-2, ∇N36 KGF-2 or ∇N35 KGF-2 (recited in claims 1 and 2), or

2) One of the following variants: a variant comprising R_1 [Asn^{71} to Pro^{203}], wherein R_1 is set forth in SEQ ID Nos:9-39, Applicant must elect one SEQ ID NO: to represent R_1 (recited in claim 1), or

3) A variant wherein at least one amino acid residue within Asn^{168} to Met^{176} of SEQ ID NO:2 is deleted, or

4) A variant comprising at least one non-native amino acid residue within Asn^{168} to Met^{176} of SEQ ID NO:2 (recited in claim 1), or

5) A variant wherein at least one amino acid residue within amino acids 85-198 of SEQ ID NO:2 is substituted (recited in claim 1), or

6) A variant wherein at least one neutral or positively charged amino acid residue within amino acids 85-198 of SEQ ID NO:2 being deleted, (recited in claim 1), or

7) A variant wherein at least one neutral or positively charged amino acid residue within amino acids 85-198 of SEQ ID NO:2 being substituted with a neutral residue or negatively charged residue, (recited in claim 1), or

8) A variant comprising the substitution of at least one amino acid residue having a higher loop forming potential for an amino acid having a lower loop forming potential within a putative loop-forming region of amino acid residues 160-164 of SEQ. ID NO:2, (recited in claim 1), or

9) A variant wherein at least one naturally-occurring cysteine at position 37, 106 or 150 of SEQ. ID NO:2 is deleted, (recited in claim 1), or

10) A variant comprising at least one naturally-occurring cysteine at position 37, 106 or 150 of SEQ. ID NO:2 being substituted with a non-native amino acid residue, (recited in claim 1), or

11) A variant comprising the addition of at least one non-native amino acid to generate an N-linked or an O-linked glycosylation site, (recited in claim 1), or

12) A variant comprising the substitution of at least one non-native amino acid to generate an N-linked or an O-linked glycosylation site, (recited in claim 1), or

13) A variant comprising a C-terminal addition of at least one domain of the constant region of a heavy chain of a human immunoglobulin, (recited in claim 1), or

14) A variant wherein residues Thr^{86}, Gly^{182}, Arg^{187} or Asn^{196} of SEQ ID NO:2 is substituted with a non-native amino acid, (recited in claim 4).

Applicant is required, in reply to this action, to elect a single variant to which the claims shall be restricted. The reply must also identify the claims readable on the elected variant, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art by their recognized divergent subject matter as defined by MPEP § 1850. Therefore, an initial lack of unity for examination purposes as indicated is proper.

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8896. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Application/Control Number: 09/284,100

Art Unit:1646

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1646
June 1, 2000

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER